

EXHIBIT 1

IN THE CIRCUIT COURT FOR KNOX COUNTY, TENNESSEE

STATE OF TENNESSEE,)
ex rel. HERBERT H. SLATERY III,)
ATTORNEY GENERAL and REPORTER,)
Plaintiff,)
v.)
PURDUE PHARMA L.P.,)
a foreign limited partnership,)
Defendant.)

FILED
CHARLES D. SUSANO III
CLERK

2019 FEB 22 AM 10:50

KNOX COUNTY CIRCUIT
CIVIL SESSIONS
AND JUVENILE COURTS

Case No. 1-173-18

ORDER

In this case, the State of Tennessee makes various allegations against Purdue Pharma L.P. ("Purdue") related to Purdue's marketing of opioid medications, including OxyContin, Butrane, and Hysingla ER. The State alleges that Purdue's marketing is in violation of the Tennessee Consumer Protection Act, Tenn. Code Ann. §47-18-104(a), (b); is in violation of a 2007 Agreed Final Judgment between the parties; and constitutes a common law public nuisance. Purdue has filed a motion to dismiss, contending that it cannot be liable for its proper promotion of FDA-approved medication and that the State's Complaint does not adequately plead causation or public nuisance. For the reasons set forth herein, Purdue's motion is denied.

I. STANDARD OF REVIEW

When considering a motion to dismiss for failure to state a claim upon which relief can be granted, the Court is limited to an examination of the complaint alone. *See Walcotts Fin. Serv., Inc. v. McReynolds*, 807 S.W. 708, 710 (Tenn. Ct. App. 1990). Such a motion avers that the allegations in the complaint, when considered alone and taken as true, are insufficient to state a claim as a matter of law. *See Cornpropst v. Sloan*, 528 S.W.2d 188 (Tenn. 1975). In other words,

such a motion tests the legal sufficiency of the complaint, not the strength of the plaintiff's proof. *See Bell ex rel. Snyder v. Icard*, 986 S.W.2d 550, 554 (Tenn. 1999). The Court is required to construe the complaint liberally in favor of the plaintiff, taking all the allegations of fact therein as true. *See Cook ex rel. Uithoven v. Spinnaker's of Rivergate, Inc.*, 878 S.W.2d 934, 938 (Tenn. 1994).

II. PREEMPTION

Purdue first contends that the Complaint should be dismissed because federal law preempts the State's claims. It is well-established that states possess sovereignty "concurrent with that of the Federal Government, subject only to the limitations imposed by the Supremacy Clause" of the United States Constitution. *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). The Supremacy Clause provides that federal law "shall be the supreme Law of the Land." (U.S. Const. art. VI, cl. 2). Thus, when state law and federal law conflict, federal law controls, and Purdue's argument is based on this conflict preemption. Conflict preemption only occurs "where it is impossible for a private party to comply with both state and federal requirements" or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quotations and citations omitted). A motion to dismiss based on preemption should only be granted when "the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Galper v. LP Morgan Chase Bank, NA*, 802 F.3d 437, 444 (2d Cir. 2015).

Importantly, the United States Supreme Court has held that "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Those police powers include protecting consumers against deceptive business practices. *See California*

v. *ARC Am. Corp.*, 490 U.S. 93, 101 (1989). When the issue is one that is traditionally the subject of state control, courts must “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Id.*

Synthesized, Purdue’s argument is that the Food and Drug Administration (“FDA”), via the Federal Food, Drug, and Cosmetic Act (“FDCA”), controls prescription medication warning labels; that Purdue’s labels complied with FDCA requirements; and that the State is seeking to impose state law liability on Purdue when federal law controls. The Court finds that Purdue’s argument is based upon a mischaracterization of the State’s Complaint, which is not grounded in the content of the medication labels but rather the conduct of Purdue and its pharmaceutical sales representatives.

For example, Purdue contends that the State’s Complaint regarding dosing limitations conflicts with the FDA’s decision not to recommend a maximum duration of use for the medications. However, the Complaint alleges that Purdue’s sales representatives incorrectly asserted that OxyContin had no dose ceiling at all:

58. Purdue represented without qualification that OxyContin did not have a dose ceiling when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

59. OxyContin has a dose ceiling that is imposed by adverse reactions to patients taking increased doses of the drug, including overdose, respiratory depression, somnolence, addiction, and other serious adverse effects.

60. While the FDA approved a limited statement on OxyContin’s Full Prescribing Information making clear that OxyContin’s dose ceiling *was* imposed by adverse reactions, Purdue’s Tennessee sales representatives routinely asserted that OxyContin had no dose ceiling *at all*. Further, Purdue failed to discipline or correct sales representatives who made such claims.

(Complaint) (emphasis original). Similarly, regarding the State’s claim that Purdue pushed the concept of “pseudoaddiction” in order to increase prescriptions, Purdue contends that its FDA-

approved label addresses these concerns. However, the State's allegation is that Purdue invented and pushed the concept of pseudoaddiction (which Purdue described as "the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors")¹ for the purpose of getting around the FDA-required language regarding red flags for drug-seeking behaviors.

Purdue further takes issue with the State's allegations regarding Purdue's use of screening tools and failure to disclose the efficacy of OxyContin use beyond twelve weeks. Again, the State has not alleged liability for Purdue's use of the FDA-mandated Risk Evaluation and Mitigation Strategy Program; rather, the State alleges that "[i]n order to make health care providers more willing to prescribe its addictive opioid products, Purdue overstated the efficacy of abuse and diversion mitigation tools like patient contracts, urine drug testing, pill counts, and similar strategies" and that a 2016 CDC Guideline "confirms the lack of adequate substantiation to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk." (Complaint, ¶¶93, 96). The Complaint then gives specific examples of ways in which Purdue allegedly overstated the efficacy of abuse prevention programs, including the use of a "General Objection Handler" to address provider concerns, as well as specific notes from sales representatives documenting their touting of the various screening tools. In addition, the Complaint alleges that Purdue "downplayed the increased risk of addiction from higher doses of its opioid products through material omissions" and "failed to disclose the material fact that there is an increased risk of addiction at higher doses of its opioid products." (Complaint, ¶¶ 139, 140).

¹ Complaint, ¶79.

In sum, Purdue’s argument with respect to preemption is based upon its erroneous assertion that the Complaint seek to hold it liable for actions that were approved or required by the FDA and the FDCA. In reality, the Complaint seeks to hold Purdue liable for alleged misleading and deceptive practices in violation of Tennessee’s Consumer Protection Act and actions that constitute Tennessee’s common law tort of public nuisance. Thus, the Court concludes that the State’s claims do not conflict with FDA and FDCA requirements, and preemption does not apply.

III. THE 2007 AGREED FINAL JUDGMENT

Purdue also seeks dismissal of the State’s claim that Purdue violated portions of a 2007 Agreed Final Judgment between the parties. The Judgment required Purdue to stop promoting and marketing off-label uses for OxyContin and to establish and implement an abuse and diversion detection program to identify providers who were over-prescribing OxyContin. Upon discovery of these “red-flag” providers, Purdue was obligated to “take further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.” (Agreed Final Judgment, ¶13). Purdue characterizes the State’s Complaint as alleging that “the 2007 Agreed Judgment requires Purdue to stop promoting opioid medication for long-term treatment of chronic pain.” Purdue contends that the State is judicially estopped from making claims of misrepresentation based on statements that were permitted or required by the Agreed Judgment.

The Court again disagrees with Purdue’s characterization of the Complaint. The State has not alleged that Purdue is liable for promoting opioids in a manner consistent with FDA requirements, nor has the State alleged liability for promotion of Purdue’s products in accordance

with the 2007 Agreed Final Judgment. Rather, the State has alleged that Purdue was required but failed to stop promoting its products to specific health care providers or otherwise failed to take any appropriate action once Purdue had knowledge of behaviors indicative of over-prescribing. The Complaint describes in great detail the specific factual bases for these allegations- in fact, these allegations comprise the bulk of the 273-page complaint. The State describes and names specific red-flag providers and explains when, how, and why Purdue continued to market to these providers, as well as Purdue's alleged failure to take the steps required in paragraph 13 of the Agreed Final Judgment. The Complaint adequately states a claim for relief for violation of the 2007 Agreed Final Judgment.

IV. TENNESSEE CONSUMER PROTECTION ACT

Purdue seeks dismissal of the Tennessee Consumer Protection Act ("TCPA") claim, contending that the State has failed to adequately plead causation. The Tennessee Supreme Court explained the purpose and construction of the TCPA in *Faye v. Vincent*, 301 S.W.3d 162, 177-78 (Tenn. 2009):

The Tennessee Consumer Protection Act, enacted in 1977, was passed, in part, to protect consumers from unfair and deceptive acts and practices occurring "in the conduct of any trade or commerce" in the state and to provide a means "for maintaining ethical standards of dealing between persons engaged in business and the consuming public." Tenn. Code Ann. § 47-18-102(2),-102(4). The Act is to be liberally construed in order to enable it to protect the consumer and to promote the other policies which motivated its passage. Tenn. Code Ann. § 47-18-102; *Myint v. Allstate Ins. Co.*, 970 S.W.2d at 926; *Morris v. Mack's Used Cars*, 824 S.W.2d 538, 540 (Tenn. 1992); *see also* Tenn. Code Ann. § 47-18-115 (noting that the Act is "remedial legislation" which would be construed to effectuate its purposes). It is also to be construed consistently with the Federal Trade Commission and federal courts' interpretations of the Federal Trade Commission Act. Tenn. Code Ann. § 47-18-115. The Tennessee Consumer Protection Act forbids "unfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. § 47-18-104(b).... The Act defines "trade," "commerce," or "consumer transaction" as "the advertising, offering for sale, lease or rental, or distribution of any goods, services, or property, tangible or intangible, real, personal, or mixed,

and other articles, commodities, or things of value wherever situated.” Tenn. Code Ann. § 47-18-103(11).

A “deceptive act or practice” under the TCPA is “one that causes or tends to cause a consumer to believe what is false or that misleads or tends to mislead a consumer as to a matter of fact.” *Tucker v. Sierra Builders*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005).

Purdue first contends that the State failed to plead an ascertainable loss of money or property. In response, the State contends that at least part of its claim is based on the TCPA’s enforcement provision, not its private right of action. The State is correct that the TCPA’s enforcement provision, Tenn. Code Ann. § 47-18-108, does not require that a person suffer an ascertainable loss. The enforcement provision provides as follows: “Whenever the division has reason to believe that any person has engaged in, is engaging in, or, based upon information received from another law enforcement agency, is about to engage in any act or practice declared unlawful by this part and that proceedings would be in the public interest, the attorney general and reporter, at the request of the division, may bring an action in the name of the state against such person to restrain by temporary restraining order, temporary injunction, or permanent injunction the use of such act or practice.” Tenn. Code Ann. § 47-18-108(a)(1). Thus, to the extent the State’s Complaint seeks injunctive relief, civil penalties, and other remedies contemplated by the enforcement provision of the TCPA, the State correctly asserts that pleading an ascertainable loss of money or property is not required.

In addition to the enforcement provision, however, the State acknowledges that it also seeks recovery of ascertainable losses as a remedy under Tenn. Code Ann. § 47-18-108(b)(1). An “ascertainable loss” is broadly defined in the TCPA as “[a]n identifiable deprivation, detriment, or injury arising from … any unfair, misleading, or deceptive act or practice even when the precise amount of the loss is not known. Whenever a violation of this part has occurred, an ascertainable

loss shall be presumed to exist.” Tenn. Code Ann. § 47-18-2102(1). Purdue’s objection to the Complaint is that the State has failed to adequately causally link the alleged deceptive behavior to any such ascertainable loss. The Court disagrees. As set forth in the State’s response to Purdue’s motion, “the Complaint alleges Purdue made widely-disseminated, deceptive, and express health and safety claims, material omissions of health and safety information, and material omissions of Purdue’s financial connections to third-party groups it substantially funded,” and that, as a result, persons purchased Purdue’s opioid products. The State then alleges that Purdue’s conduct “led to addiction, abuse, diversion, and other negative outcomes that have caused the State and its political subdivisions to spend substantial resources to attempt to address.” (Complaint, ¶ 874). The State further alleges that it and its political subdivisions “have spent significant public resources on treatment, toxicology reports and autopsies, law enforcement, corrections, intervention programs, drug courts, prosecution, probation, and child welfare related to opioids, OxyContin, and heroin and more funds are needed to address this public health crisis.” (Complaint, ¶ 909). At this juncture, the Court does not inquire into whether the State can actually prove its assertions. It must assume the State’s assertions are true and determine whether the assertions state a claim for relief. The Court finds that the State has properly pleaded a claim for violation of the Tennessee Consumer Protection Act.

V. PUBLIC NUISANCE

Finally, Purdue seeks dismissal of the State’s public nuisance claim and contends that the States seeks to hold Purdue liable for a sweeping array of societal harms that have occurred as a result of the opioid crisis. Purdue contends that the Complaint fails to adequately plead causation, that the derivative injury rule applies, and that the State does not allege an interference with any right common to the public.

A public nuisance is an act or omission that unreasonably interferes with or obstructs rights common to the public. *See Metropolitan Gov't of Nashville v. Counts*, 541 S.W.2d 133, 138 (Tenn. 1976); Restatement (Second) of Torts §821B (1977). In *Sherrod v. Dutton*, 635 S.W.2d 117, 119 (Tenn. Ct. App. 1982), the Tennessee Court of Appeals explained that a nuisance “extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable and comfortable use of property.” (Citations omitted); *see also State ex rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975) (defining a public nuisance as “a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law.”) (Citations omitted).

With respect to causation, the Court finds that the complaint is adequately pleaded. As has been set forth previously, the Complaint describes with great specificity the actions of Purdue with respect to its marketing of opioid products, including alleged misrepresentations regarding the safety, efficacy, and benefits of its products and an alleged practice of marketing its products to known “pill mills.” The Court will not rehash the allegations, but the Complaint is replete with specific examples of behavior on the part of Purdue that, if proven, would establish interference with the health, comfort, and safety of the citizens of the State of Tennessee. Furthermore, the Complaint alleges resulting damages, including but not limited to “increased opioid use, abuse, addiction, and overdose deaths” and “[t]he greater demand for emergency services, law enforcement, addiction treatment, and other social services,” which place “an unreasonable burden on governmental resources including the State and its political subdivisions.” (Complaint, ¶ 960, 961).

Purdue further argues that intervening and superseding acts prohibit a finding of causation. Specifically, Purdue contends that any alleged nuisance was caused not by Purdue's sale of its medications but rather by doctors who wrote "improper prescriptions" and/or by third parties who allowed persons without prescriptions to obtain opioid medications illegally. However, the State's Complaint alleges that the foregoing acts were foreseeable and made possible by Purdue's acts. In addition, "[t]here is no requirement that a cause, to be regarded as the proximate cause of an injury, be the sole cause, the last act, or the one nearest to the injury, provided it is a substantial factor in producing the end result.... An intervening act will not exculpate the original wrongdoer unless it appears that the negligent intervening act could not have been reasonably anticipated."

McClenahan v. Cooley, 806 S.W.2d 767, 775 (Tenn. 1991).

Purdue contends that the Complaint should be dismissed because "where a plaintiff's injuries are wholly derivative of harm to a third party, the injuries are generally deemed indirect and consequently, too remote as a matter of law to support recovery." *Steamfitters Local Union No. 614 Health & Welfare Fund v. Philip Morris, Inc.*, 2000 WL 1390171 (Tenn. Ct. App. Sept. 26, 2000). However, the Complaint seeks damages for injuries to the State, not for the injuries of those who have become addicted to opioids. Purdue's reliance on the *Steamfitters* case is misplaced. In that case, the union's Health and Welfare Fund sued tobacco companies to recover money spent by the Fund to treat its members' smoking-related illnesses. The premise of the Fund's claim was that the tobacco companies' activities prevented the Fund from implementing programs to educate its participants on the addictive qualities of tobacco. Ultimately, the Court of appeals held that "it would be 'virtually impossible' for the Funds to prove with reasonable certainty the effect education or smoking cessation programs would have had on the physical injuries suffered by plan participants since the damages stem from individual smokers' decisions

whether to continue smoking and, if so, how frequently to smoke.” *Id.* at *6. The Court noted that “it would be the sheerest sort of speculation to determine how these damages might have been lessened had the Funds adopted the measures defendants allegedly induced them not to adopt.” *Id.* (citing *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 238-39 (2d Cir. 1999)).

The allegations in the present case are wholly different in that they are not based upon the State being fraudulently induced to inaction, nor does the State seek damages for the physical injuries of the individual opioid users. Rather, the State seeks damages sustained by it and its political subdivisions as a direct result of Purdue’s alleged marketing activities designed to increase prescriptions. The claims are simply different.

Lastly, Purdue contends that the Complaint must be dismissed because the State does not allege interference with any right common to the public, “such as clean air or water.” Purdue’s argument takes too narrow a view of public nuisance. As set forth above, a public nuisance can encompass virtually anything that endangers life or health. In fact, the Tennessee Supreme Court has deemed a church’s handling of snakes to be a public nuisance:

Under this record, showing as it does, the handling of snakes in a crowded church sanctuary, with virtually no safeguards, with children roaming about unattended, with the handlers so enraptured and entranced that they are in a virtual state of hysteria and acting under the compulsion of “anointment”, we would be derelict in our duty if we did not hold that respondents and their confederates have combined and conspired to commit a public nuisance and plan to continue to do so. The human misery and loss of life at their ‘Homecoming’ of April 7, 1970 is proof positive.

Our research confirms the general pattern. Tennessee has the right to guard against the unnecessary creation of widows and orphans. Our state and nation have an interest in having a strong, healthy, robust, taxpaying citizenry capable of self-support and of bearing arms and adding to the resources and reserves of manpower. We, therefore, have a substantial and compelling state interest in the face of a clear and present danger so grave as to endanger paramount public interests.

Pack, 99 S.W.2d at 113-14.

In the present case, the State's Complaint alleges that Purdue engaged in misleading and deceptive marketing practices for the purpose of increasing opioid prescriptions and that, as a result, Purdue created an opioid epidemic that has endangered the health and safety of the citizens of Tennessee and has resulted in financial loss to the State. The Complaint adequately states a claim for public nuisance.

V. CONCLUSION

Having carefully considered the arguments set forth in Purdue's motion to dismiss, the Court finds that the State's Complaint sets forth a cause of action for violation of the Tennessee Consumer Protection Act, violation of the 2007 Agreed Final Judgment, and public nuisance. Accordingly, Purdue's motion to dismiss is respectfully **DENIED**.

Entered this 22 day of February, 2019.


JUDGE KRISTI M. DAVIS

CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify pursuant to Rule 58, Tenn. R. Civ. P., that a copy of this ORDER has been served on all parties or their counsel of record by mail.

This 22 day of Feb -, 2019.

Charles D. Susano, III
Knox County Circuit Court Clerk

By:


R. Keen
Deputy Clerk